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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,728	01/17/2002	John Victor Lamont	111723	2576

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,728	LAMONT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 6-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 14 April 2004 in which claims 1 and 4 were amended and claim 5 was canceled. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 14 November 2003, not reiterated below, are withdrawn in view of the amendments or Applicant's Arguments. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 1, 3-4, 6-14 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 6-10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiekowsky et al (U.S. Patent No. 6,090,555, issued 18 July 2000).

Reiterated from Previous rejection:

Regarding Claim 1, Fiekowsky et al disclose a method for imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array the method comprising imaging the array and detecting a signal from a first molecule located on the solid support at a known position within the array (i.e. control probes, Column 7, lines 43-63), by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site and determining the amount of detectable signal (measure fluorescence intensity) in each window to thereby detect the presence of molecules (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38) and wherein the reaction site defines a corner within which the first molecule is located i.e. (Column 7, lines 55-60 and Fig. 9A).

Regarding Claim 4, Fiekowsky et al disclose the method wherein after detecting a first molecule the first inspection window is repositioned so that one or more of the discrete reaction sites are also located within the window detecting the one or more sites and by reference to the first molecule aligning a further inspection window (Column 9, line 30-Column 10, line 39 and Fig. 12-13).

Regarding Claim 6, Fiekowsky et al disclose the method wherein step (i) further comprises detecting a second molecule located on the solid support at a known position with respect to the array and aligning the inspection windows by reference to both first and second windows (i.e. at each corner, Column 7, lines 59-60)

Regarding Claim 7, Fiekowsky et al disclose the method wherein the imaging is carried out by detecting emitted radiation (Column 7, lines 1-16).

Regarding Claim 8, Fiekowsky et al disclose the method wherein the radiation is chemiluminescent, bioluminescent or fluorescent (Column 4, lines 7-17).

Regarding Claim 9, Fiekowsky et al disclose the method wherein the molecules of the array are capable of reacting with an analyte i.e. hybridize to (Column 6, lines 59-67).

Regarding Claim 10, Fiekowsky et al disclose the method wherein the molecules of the array are polynucleotides (Column 6, lines 59-67).

Regarding Claim 14, Fiekowsky et al disclose the method wherein the signal detection of step (i) must be above a pre-defined value in order to proceed i.e. brightness (Column 8, lines 3-32 and Fig. 8).

Response to Arguments

4. Applicant argues that Fiekowsky fails to disclose the claimed invention, but instead describes a method of scanning images that requires line-by-line scan and hence their method requires use of a reference pattern separate from the array to obtain an analysis with a high degree of accuracy. In contrast, Applicant states, the instant method uses a reference point located in a corner of the array. The argument has been considered but is not found persuasive. First, Applicant has not pointed to a teaching in the Fiekowsky reference that supports the assertion that their method requires line-by-line scanning. However, even if the Fiekowsky method requires scanning as asserted, the open claim language "comprising" in the instant claims encompasses any additional steps (e.g. scanning) taught in the prior art. Second, arguments regarding the "high degree of accuracy" and "false positive recognitions" are not limitations within the instant claims. Hence, arguments concerning these characteristics are not commensurate in scope with the claims. Finally, as stated above, Fiekowsky teaches imaging an array, detecting a signal from a molecule located in corner of the array, referencing the molecule to align an inspection window and determining the amount of detectable signal to detect the presence of molecules as claimed (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38).

5. Claims 1 and 4, 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Reiterated from Previous rejection:

Regarding Claim 1, Noblett discloses a method of imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array, said molecules being detectably labeled (Column 6, lines 64-67) comprising: imaging the array and detecting a signal representing a first molecule located on the solid support at a known position (i.e. fiducial mark, Column 5, lines 32-56) by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites (Column 3, lines 32-35) and determining the amount of detectable signal in each window (Column 3, lines 24-35; Column 7, lines 21-67 and Claims 13-16) wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching (scanning) within the window for an image of the first molecule (Column 7, line 21-Column 8, line 4) wherein the first molecule is located a corner of the array (Column 7, line 21-Column 8, line 4 and Fig. 2 & 7).

Regarding Claim 4, Noblett discloses the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 7, line 61-Column 8, line 4 and Claim 15).

Regarding Claim 6, Noblett discloses the method further comprising detecting a second molecule (i.e. fiducial) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 7, lines 61-66).

Regarding Claim 7, Noblett discloses the method wherein imagining is carried out by detecting emitted radiation (Column 7, lines 31-43 and Claim 13).

Regarding Claim 8, Noblett discloses the method wherein the radiation is fluorescent (Column 4, lines 35-49 and Claim 13).

Regarding Claim 9, Noblett discloses the method wherein the molecules of the array are capable of reacting with an analyte i.e. genetic material (Column 3, lines 50-53 and Claims 3-4).

Regarding Claim 10, Noblett discloses the method wherein the molecules of the array are polynucleotides i.e. genetic probe material (Column 3, lines 50-53 and Claims 3-4).

Response to Arguments

6. Applicant argues that Noblett teaches a microarray including a fiducial mark functions as a reference point for positioning and aligning the substrate but does not teach a reference point in the corner of the array as claimed. Applicant defines the fiducial marks of Noblett as being on the substrate, not on the array section of the substrate. Applicant appears to be arguing that the instantly claimed "array" encompasses only the arrayed molecules and not the support on which the molecules are spotted. However, the claims are not so limited. The claims are drawn to imaging an array of discrete reaction sites on the surface of the solid support. Neither the claims or the specification define an array as consisting of reaction sites and not encompassing the surface. Furthermore, Noblett teaches an array of reaction sites on the array (e.g. Fig. 2) wherein reference molecule is in a corner of the array (i.e. x and y offsets with minimal distance between the fiducials, Column 3, lines 29-32 e.g. #125 & #127, Fig. 2). Hence Noblett teaches the array as claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiekowsky et al (U.S. Patent No. 6,090,555, issued 18 July 2000) in view of Juncosa et al (U.S. Patent No. 6,309,601, filed 1 May 1997).

Regarding Claim 3, Fiekowsky et al disclose a method for imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array the method comprising imaging the array and detecting a signal from a first molecule located on the solid support at a known position within the array (i.e. control probes, Column 7, lines 43-63), by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site and determining the amount of detectable signal (measure fluorescence intensity) in each window to thereby detect the presence of molecules (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38) wherein the first inspection window defines a two-dimensional array of pixels and scanning is carried out by scanning the array of pixels and determining values for the pixels (Column 8, lines 33-58) wherein adjacent pixels are scanning e.g. 1-9 (Column 8, lines 50-58) which clearly suggests that the pixels 1-9 are scanned in any order but they do not specifically teach diagonal scanning. However, diagonal scanning was known in the art at the time the claimed invention was made as taught by Juncosa (Fig. 6A) wherein it is taught that diagonal scanning is preferred (Column 11, lines 18-20). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diagonal scanning of Juncosa et al to the scanning of pixels 1-9 of Fiekowsky et al based on their suggestion (Column 8,

lines 50-58) and further based on the preferred teaching of Juncosa (Column 11, lines 18-20). As such one of ordinary skill would have been motivated to diagonally scan the array of Fiekowsky et al with a reasonable expectation of success.

Response to arguments

9. Applicant argues that Juncosa does not teaches diagonal scanning. The argument has been considered but is not found persuasive because as cited above, Juncosa illustrates (Fig. 6A) the scanning path (i.e. scan lines #240, Column 11, lines 13-15). The scan lines illustrated are clearly diagonal to the four cornered array of reaction sites. Hence, Juncosa meets the limitations of the claim.

Applicant further argues that neither Fiekowsky or Juncosa teach the elements of Claim 1 and hence their combination cannot render Claim 3 obvious. The argument has been considered but is not found persuasive for the reasons stated above regarding Fiekowsky.

10. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiekowsky et al (U.S. Patent No. 6,090,555, issued 18 July 2000) in view of Pirrung et al (U.S. Patent No. 5,143,854, issued 1 September 1992).

Regarding Claims 11-13, Fiekowsky et al disclose a method for imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array the method comprising imaging the array and detecting a signal from a first molecule located on the solid support at a known position within the array (i.e. control probes, Column 7, lines 43-63), by reference to the first molecule aligning an individual inspection window in registration with each discrete reaction site and determining the amount of detectable signal (measure fluorescence intensity) in each window to thereby detect the presence of molecules (Column 5, lines 5-28; Column 6, line 59-Column 7, line 67; and Column 10, lines 6-38).

Furthermore, they teach the array are made using VLSIPS™ technology as taught by Pirrung in U.S. Patent No. 5,143,854 (Column 1, lines 51-56 and Column 3, lines 26-29) but they do not specifically teach the solid support is less than 1 cm^2 (Claim 11) wherein the solid support is ceramic, silicon or glass (Claim 12), or that the molecules are covalently attached to the solid support (Claim 13).

Pirrung et al teaches the VLSIPS™ technology wherein the support is less than 1 cm^2 (Column 15, lines 49-68 and Column 29, lines 28-42) wherein the solid support is made of silicon or glass (Column 11, lines 14-40) and wherein the molecules are covalently attached to the support (Column 3, lines 8-33 and Fig 14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the VLSIPS™ technology as taught by Pirrung to the substrate of Fiekowsky et al and to covalently attach the molecules to a substrate of less than 1 cm^2 and made of silicon or glass based because one of ordinary skill would have been motivated to use the preferred substrate for successful VLSIPS™ array production.

Response to arguments

11. Applicant argues that neither Fiekowsky or Pirrung teach the elements of Claim 1 and hence their combination cannot render Claims 11-13 obvious. The argument has been considered but is not found persuasive for the reasons stated above regarding Fiekowsky.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check

PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 18, 2004